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| APPLICATION NO.                                                                         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/719,320                                                                              | 11/21/2003  | Kenneth James Kozak  | 100736/0504851      | 3081             |
| 26874                                                                                   | 7590        | 05/04/2006           | EXAMINER            |                  |
| FROST BROWN TODD, LLC<br>2200 PNC CENTER<br>201 E. FIFTH STREET<br>CINCINNATI, OH 45202 |             |                      | TONGUE, LAKIA J     |                  |
|                                                                                         |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                         |             |                      | 1645                |                  |

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                             |  |
|------------------------------|--------------------------------------|---------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/719,320 | <b>Applicant(s)</b><br>KOZAK, KENNETH JAMES |  |
|                              | <b>Examiner</b><br>Lakia J. Tongue   | <b>Art Unit</b><br>1645                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                                    |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/9/06, 8/22/05</u> | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Applicant's response filed on January 9, 2006 is acknowledged. Claims 1-16 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

#### ***Rejections Withdrawn***

1. In view of applicants' response the rejection under 35 U.S.C. 102(e) as being anticipated by Reiter et al (US 2004/0023316 A1) on page 3, paragraph 4 is withdrawn.

#### ***Rejections Maintained***

2. The rejection of claims 1-10 and newly amended claims 11-16 under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons set forth in the previous office action on page 4, paragraphs 8-10.

Applicant urges that the term "specific", when used in context of the present specification in the phrase *H. pylori* antigens antibodies inherently means specific to *H. pylori*.

It is the examiners position that the term "specific" includes a continuum of specificity and is not limited to the absolute lack of reactivity with other strains and species as now claimed. Moreover, the claims as amended recite new matter. The limitation "wherein such antigen specific antibodies bind to *H. pylori* antigens and do not

react with different species and strains of *Helicobacter* or *Campylobacter*" is new matter.

The examiner is unclear applicants' grounds for a) wherein antigen specific antibodies bind to *H. pylori* antigens and do not react with different species and strains of *Helicobacter* or *Campylobacter* and b) an antibody being genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen.

The newly added claim language conflicts with what applicant has disclosed in the instant specification. The instant specification submits that one problem with immunoassays is its cross-reactivity. Moreover, applicant submits that the antigens of *H. pylori*, in particular, the putative flagella protein, have shown that some of these antigens are not specific to *H. pylori* and are also found in other bacteria such as *C. jejuni* and *C. coli* (0005). While the antigen may be specific for *H. pylori*, the same antigen may also be cross-reactive with *Campylobacter*. How will applicant know that the antigen is truly specific for *H. pylori* and that it will not cross-react. Further, Sato (*Helicobacter pylori* in culture: an ultrastructural study, *Hokkaido Igaku Zasshi*, 2000; 75(3): 187-96) did a studying using *H. pylori* 43504, which is the same genus and specie as that in the instant specification, to teach that flagella with a sheath originated from a concave depression at the end of the organism frequently attaches to adjacent organisms. Where in the instant specification has applicant provided support for the claims as amended? Has applicant shown that *H. pylori* antigens do not cross-react with different species and strains of *Helicobacter* or *Campylobacter*?

Regarding applicants' recitation of an antibody being a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen, the examiner is not sure how this is accomplished. The instant specification submits that genus specific monoclonal antibodies can cross-react with different species and strains of *Helicobacter* or *Campylobacter* (0013). How is the recited limitation factual? How does cross-reactivity take place and applicant still be able to have a specific antibody capable of binding to *H. pylori* antigens. No original descriptive support for the claimed invention could be found in the instant specification.

Lastly, the examiner would like to point applicants' attention to (0019) where applicant submits that cross-reactivity can be addressed/reduced in the formulation of the *H. pylori* specific antibody solutions by buffering and formulating the wash with the addition of salts and surfactants to control cross-reactivity.

### ***New Grounds of Rejection***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner is unclear what applicant intends by

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"mixtures thereof". Does applicant mean a mixture of monoclonal antibodies, a mixture of polyclonal antibodies or a mixture of both monoclonal and polyclonal antibodies?


***Conclusion***

4. No claims are allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
EJT  
4/14/06

  
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